K092149

510(k) SUMMARY (per CFR21 807.92(c))

GENERAL INFORMATION:

MAR 18 2010

510k Owner's Name **Address**	Bovie Medical 5115 Ulmerton Road Clearwater, Florida 33760-4004
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 384-2323 FAX Number: (727) 347-9144
Date Prepared:	March 9, 2010

DEVICE DESCRIPTION:

Trade Name:	BOSS Bipolar Operative Saline-Enhanced Sintered Steel Coagulation Device
Common Name:	Resection (Cutting and Coagulation) Device
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code: GEI)

DEVICE DESCRIPTION:

Predicate Devices:

TissueLink: Aquamantys 2.3 Bipolar Sealer	K-052859
TissueLink: Aquamantys 6.0 Bipolar Sealer	K-052859

510(k) SUMMARY (per CFR21 807.92(c))

INTENDED USE:

BOSS Bipolar Operative Saline-Enhanced Sintered Steel Coagulation devices are sterile, single-use bipolar electrosurgical devices intended to deliver RF energy and saline for coagulation of soft tissue and bone at the operative site. It is intended for but not limited to orthopaedic, spine, endoscopic procedures, abdominal and thoracic surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization.)

DEVICE COMPONENTS AND OPERATION:

1) Insulated Handle:

The Insulated Handle encases the shaft and tip and one of the controlling mechanisms for the flow of saline. The activation of RF current is accomplished by footswitch.

There are two flow control mechanisms so the flow of saline (one directly on the handle and a roller clamp just proximal to the handle). Saline flow can be regulated by the user within the sterile field. The saline delivery tubing is approximately ten (10) feet in length and incorporates an I.V. spike on the end to attach directly to a hanging IV (saline) bag.

The Handle power cord is approximately ten (10) feet in length and incorporates a 3-prong electrical plug.

The insulation on the Handle and Power Cord meets the requirements for Dielectric Withstands of Accessories.

2) Shaft and Electrode Tip:

The electrode tip delivers RF energy for coagulation and delivers saline which is gravity-fed from an intravenous bag to the tip. There are three handle shape configurations: straight shaft, angled shaft, and laparoscopic shaft. Each is constructed of the same materials.

510(k) SUMMARY (per CFR21 807.92(c))

These devices use technology substantially equivalent to the Aquamantys SS4.0 Bipolar Sealer (K-063639) and the Aquamantys 6.0 Bipolar Sealer (K-052859). Both consist of an electrode tip that is used to coagulate tissue through the utilization of high frequency radiofrequency energy and saline.

BOSS Bipolar Operative Saline-Enhanced Sintered Steel Coagulation devices are provided sterile, sterilized using ethylene oxide gas, and are for single use only.

These devices conform to the requirements of safety standard IEC 60601-2-2. There are no significant differences in technology, performance, or intended use between BOSS Bipolar Operative Saline-Enhanced Sintered Steel Coagulation devices and predicate devices. There are no new questions raised regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 18 2010

Bovie Medical
% Mr. Richard A. Kozloff
Vice – President, Quality Assurance/Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760-4004

Re: K092149
Trade Name: BOSS Bipolar Operative Saline-Enhanced Sintered Steel) Coagulation Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 9, 2010
Received: March 10, 2010

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): _____

Device Name: BOSS Bipolar Operative Saline-Enhanced Sintered Steel Coagulation Device

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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